

REMARKS

Status of the Claims/Claim Amendments

Claims 7, 14 and 15 have been amended. Support for the claim amendments may be found throughout the specification and original claims as filed. *See, e.g.*, Specification, page 5, paragraph [018]; original claim 7. Applicants respectfully request entry of the foregoing above amendment and submit that the above amendment does not constitute new matter.

Claims 10 and 16 have been canceled herein without prejudice or disclaimer to the subject matter therein. Claims 17-20 have been withdrawn by the Examiner. Accordingly, upon entry of the foregoing amendments, claims 1-9, 11, 13-15 and 17-21 will be pending.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 7 and 14 stand rejected as failing to comply with the written description requirement under 35 U.S.C. § 112, 1st paragraph.

The Office Action asserts that the specification does not provide adequate written description for “derivatives and solvates.” Office Action, page 3.

Applicants respectfully disagree and traverse this rejection. Nonetheless, in an effort to expedite prosecution, Applicants have amended claim 7 to recite that “the strontium cation is provided by a strontium dichloride, strontium sulfates, or an organic strontium derivative, wherein said organic strontium derivative is strontium acetylacetonate or strontium ranelate.” Applicants have also amended claim 14 to recite that “the strontium cation is provided by a strontium dichloride.”

In view of the foregoing amendments, Applicants respectfully request withdrawal of this rejection.

Claim 10 stands rejected as failing to comply with the enablement requirement under 35 U.S.C. § 112, 1st paragraph.

Applicants respectfully disagree and traverse this rejection. Nonetheless, Applicants have canceled claim 10. Accordingly, this rejection is moot.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 7 and 14-16 stand rejected under 35 U.S.C. § 112, 2nd paragraph as being indefinite.

Claim 7 is rejected over the term “strontium cation.” The Office Action states that claim 7 uses this term “to mean ‘strontium cation or strontium salt,’ while the accepted meaning is ‘a positively charged ion of strontium.’” *Id.* at pages 8-9. The Office Action recognizes that Applicants may be their own lexicographer, but that “the specification does not clearly redefine the term.” *Id.*

Applicants respectfully disagree and traverse this rejection. Applicants submit that one of skill in the art would understand the recitation of “strontium cation.” Nonetheless, in an effort to expedite prosecution, Applicants have amended claim 7 to recite that “the strontium cation is provided by a strontium dichloride, strontium sulfates, or an organic strontium derivative, wherein said organic strontium derivative is strontium acetylacetonate or strontium ranelate.”

In view of the foregoing, Applicants respectfully request withdrawal of the indefiniteness rejection over claim 7.

Claims 14 and 16 are rejected over the recitation of “dihalogenide” and “alcoholate,” respectively. Applicants have amended claim 14 to delete the recitation of “dihalogenide” and have canceled claim 16. Accordingly, this rejection is moot.

Rejections Under 35 U.S.C. § 103(a)

Claims 1-11, 13-16 and 21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Maurel et al. (U.S. Patent No. 6,129,924, “the ‘924 patent”) in view of Henquin (Pflugers Archive - European J. of Physiology (1980), 383: 123-129, “Henquin”).

The Office Action asserts that the ‘924 patent discloses organometallic complexes obtainable by the reaction of metal in the +2 oxidation state, sitosterol or a plant extract containing sitosterol, and a diglyceride of a formula falling within the claimed invention. Office Action, page 10. The Office Action, however, acknowledges that “[t]he ‘924 patent does not disclose the specific cation of metal in the +2 oxidation state, strontium.” *Id.* at page 12.

To remedy the deficiencies of the ‘924 patent, the Office Action relies on Henquin. The Office Action asserts that Henquin teaches that Sr^{2+} supports glucose stimulated insulin release, but does not have the same efficiency as Ca^{2+} . *Id.* The Office Action contends that it would have been obvious to “substitute the cation of metal in the +2 oxidation state of the organometallic complexes disclosed in the ‘924 patent with strontium ions in the +2

oxidation state taught by Henquin.” *Id.* The Office Action asserts that both the organometallic complexes disclosed in the ‘924 patent and the strontium ions in the +2 oxidation state of Henquin have anti-diabetic and/or insulinomimetic activity. *Id.* The Office Action concludes that it would have been obvious “to substitute equivalents known for the same purpose.” *Id.* (citing M.P.E.P. §2144.06).

Applicants respectfully disagree and traverse this rejection.

A. A Rejection Based On Equivalency Cannot Be Maintained Where There is No Recognition Of Equivalency In The Prior Art

Part II of M.P.E.P. §2144.06, entitled, “Substituting Equivalents *Known for the Same Purpose*” makes clear that “*equivalency must be recognized in the prior art*, and cannot be based on applicant’s disclosure or the mere fact that the components at issue are functional or mechanical equivalents.” M.P.E.P. §2144.06, II (emphasis added). Therefore, to support an obviousness rejection based on equivalency, it must be established that the prior art recognized that Sr^{2+} and the metals disclosed in the ‘924 patent are equivalents.

The Office Action has not satisfied its burden. Indeed, the Office Action has not demonstrated that the prior art recognized that Sr^{2+} and the metals disclosed in the ‘924 patent are equivalents, i.e., known to be useful in forming organometallic complexes having a particular activity. The Office Action states that “strontium ions in the +2 oxidation state of Henquin have anti-diabetic and/or insulinomimetic activity.” Office Action, page 12. The Office Action, however, does not provide any support for this assertion. Rather, Henquin is silent regarding whether Sr^{2+} has anti-diabetic activity, i.e., useful in treating diabetes. Accordingly, Applicants respectfully submit that the Office Action has not established the requisite showing to support an obviousness rejection based on equivalency.

B. The ‘924 Patent Teaches Away From Using Strontium

The ‘924 patent discloses organometallic complexes that may be used to treat diabetes. *See, e.g.*, col. 10, line 63 to col. 11, line 7 (wherein the metal is vanadium, niobium, selenium, chromium and molybdenum”); col. 5, lines 44-48 (disclosing organometallic complexes having anti-diabetic activity, wherein the metal is vanadium, niobium, molybdenum, selenium, chromium, or zinc); *see also* Examples 1-8 (disclosing vanadium complexes).¹ These complexes comprise either transition metals or non-metals. These

¹ Selenium is generally considered to be a non-metal.

complexes, however, do not comprise alkaline earth metals, e.g., strontium. Indeed, nowhere in the '924 patent is there a specific teaching that an organometallic complex comprising an alkaline earth metal has anti-diabetic activity. Accordingly, the '924 patent teaches away from using alkaline earth metals such as strontium in complexes for treating diabetes.

C. One Of Ordinary Skill In The Art Would Have No Reason To Combine The '924 Patent And Henquin

The '924 patent discloses organometallic complexes having anti-diabetic activity, wherein the complexes comprise either transition metals or non-metals. Neither Henquin, nor the prior art teaches that Sr^{2+} has anti-diabetic activity. Accordingly, Applicants submit that one of ordinary skill in the art would have no reason to combine the teachings of the '924 patent and Henquin, as suggested in the Office Action, to arrive at a compound having anti-diabetic activity.

D. There Is No Reasonable Expectation Of Success Of Using Strontium For Treating Diabetes

As discussed above, the '924 patent teaches away from organometallic complexes having anti-diabetic activity, wherein the complexes comprise alkaline earth metals (e.g., Sr^{2+}). Furthermore, neither Henquin, nor the prior art teaches that Sr^{2+} has anti-diabetic activity. Accordingly, Applicants submit that at the time the invention was made there was no reasonable expectation that strontium would be effective in treating diabetes.

In view of the foregoing, Applicants respectfully request withdrawal of the obviousness rejection.

CONCLUSION

In view of the foregoing, Applicants respectfully request an indication of allowance of all claims.

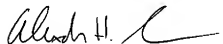
If the Examiner has any questions relating to this response, or the application in general, she is respectfully requested to contact the undersigned so that prosecution of this application may be expedited.

Respectfully submitted,

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Dated: May 23, 2008

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